REMARKS

This paper is filed in response to the office action mailed on December 16, 2004. In the office action, the restriction requirement is made final and therefore claims 8-9 and 20-30 are withdrawn from current consideration. Claims 2-3 and 11-12 have been canceled; claims 1, 10 and 16 have been amended; claims 1, 4-7, 10 and 13-19 remain pending.

The office action objects to the wording of claim 16 and claim 16 has been amended to traverse this rejection.

Turning to the rejections based upon the prior art, the office action rejects claims 1-2, 4-5, 10-11, 13 and 15-17 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,168,703 ("Kenigsberg"). In response, claims 1, 10 and 16 have been amended to include the limitations of now-canceled claims 2-3 and 11-12 thereby traversing this rejection.

Specifically, under MPEP § 2131,

> [t]o anticipate a claim, the reference must teach every element of the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.

Citing, Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Kenigsberg fails to serve as an anticipating reference for at least two reasons. First, independent claims 1, 10 and 16 require the pressure measuring device to include an elongated tube with an opening in its sidewall and a closed distal end. Claims 1, 10 and 16 also require the outer tubular sheath to have a closed distal end with the two spaced apart openings in the sidewall of the sheath. Kenigsberg does not teach or suggest this structure. The inner tube 22 of Kenigsberg as shown in Fig. 1 includes an open distal end 24. See Fig. 1 and column 4, line 59 of Kenigsberg. Further, the sheath 12 also includes an open distal end 14. See Fig. 1 and column 3, line 31.

More importantly, claims 1, 10 and 16 are directed toward an intravascular pressure measuring device. The closed end of the outer sheath is important as it enables the apparatus to be placed in the vascular system with the distal end beyond the problematic occlusions. Then, pressure readings can be taken on either side of an occlusion without

moving the device as explained in the specification on pages 2 and 5. The Kenigsberg apparatus cannot perform this function as both of its tubes 12, 22 have open distal ends.

Further, Kenigsberg is directed toward a gastroesophageal reflux diagnostic tool and is not designed for, nor can it accomplish pressure measurements on either side of an occlusion in a vascular system. Accordingly, for at least these reasons, the anticipation rejection of claims 1, 4-5, 10, 13 and 15-17 based on Kenigsberg is improper and should be withdrawn.

Next, the office action rejects claims 1-2, 6, 10 and 11 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,396,897 ("Jain"). In response, claims 10 and have been amended to traverse this rejection. Specifically, claims 1 and 10 both require the outer sheath of a closed distal end with the spaced apart openings being disposed in a sidewall of the sheath. Jain does not teach or suggest this structure as its cannula 1 clearly includes an open end 4. In addition to not satisfying the structural limitations of claims 1 and 10, Jain is clearly inappropriate as an anticipating reference as it is directed toward a biopsy needle or cannula and not a pressure measuring device. There is no way that the apparatus in Jain could be used intravascularly.

Accordingly, for at least these reasons, the anticipation rejection of claims 1, 6 and 10 based upon Jain is improper and should be withdrawn.

Next, the office action rejects claims 1, 3, 6, 10 and 12 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,358,229 ("Tihon"). In response, the limitations of now-canceled claims 2 and 11 have been added to claims 1 and 10, respectively to traverse this rejection. Tihon discloses an inner tube 30 with an open distal end 34. See Fig. 2 in column 3, line 24. Tihon does not teach or suggest an inner tube with a sidewall opening.

Further, Tihon is directed toward a urinary drain and is therefore not an intravascular device and therefore Tihon cannot anticipate amended claims 1 and 10 for this additional reason. Therefore, for at least the reasons set forth above, applicants respectfully submit that the anticipation rejection of claims 1, 6 and 10 based upon Tihon is improper and should be withdrawn.

Next, the office action rejects claims 16-18 under 35 U.S.C. § 103 as being unpatentable over Jain in view of Kenigsberg. In response, independent claim 16 has been amended to require both the inner tube and outer sheath to have closed distal ends and that

the spaced apart openings in the outer sheath be in the sidewall thereof and that the opening in the inner tube be in the sidewall thereof. The preamble of claim 16 has also been amended to make it clear that it is directed toward an intravascular device.

No hypothetical combination of Jain and Kenigsberg can establish a *prima facie* case of obviousness. Specifically, under MPEP §§ 2142 and 2143,

> [t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

Citing, In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); *see also* MPEP § 2143-§ 2143.03 for decisions pertinent to each of these criteria.

The base reference, Jain, does not disclose an outer sheath for use in an intravascular device. Instead, the outer structure of Jain is a needle or cannula used for taking biopsies. It has an open end 4. Kenigsberg, on the other hand, is also not directed toward an intravascular device, but to a device that is inserted down a patient's throat. The outer sheath 12 of Kenigsberg also has an open end 14. Thus, no hypothetical combination of Tihon and Kenigsberg teaches or suggests all of the limitations of amended claim 16 and therefore no *prima facie* case of obviousness can be established with these two references.

Further, there is simply no motivation in either the references themselves or the knowledge generally available to one skilled in the art to make the further modifications that would be necessary to Jain and Kenigsberg in order to establish a *prima facie* case of obviousness. Because neither Jain nor Kenigsberg is directed toward an intravascular device. Jain is directed toward a needle for biopsies. Kenigsberg is directed toward a gastroesophageal diagnostic tool. Neither device is used intravascularly. Therefore, one skilled in the art seeking to design and improve pressure sensing tool for use intravascularly would not even look at these two references for guidance.

Therefore, for at least the above reasons, the obviousness rejection of claims 16-18 does not meet the standards of §§ 2142 or 2143, is therefore improper and should be withdrawn.

Next, the office action rejects claims 7 and 14 under 35 U.S.C. § 103 as being unpatentable over Kenigsberg in view of U.S. Patent No. 6,259,938 ("Zarychta"). In response, claims 1 and 10 have been amended to clearly traverse this rejection. Specifically, Kenigsberg is not a proper base reference to use in any obviousness rejection of claims 1 and 10 as neither the tube 22 nor the sheath 12 of Kenigsberg has closed distal ends. The Kenigsberg structure is clearly inappropriate to use in intravascular pressure readings. Zarychta is merely cited for the proposition that it teaches the use of a radiopaque marker. Zarychta is not directed toward the two tube system of claims 1 and 10 and therefore cannot supplement Kenigsberg with respect to its structural deficiencies. Therefore, there is no way to establish a *prima facie* case of obviousness using Kenigsberg and Zarychta and therefore the obviousness rejection of claims 7 and 14 does not meet the standards of §§ 2142 and 2143, is therefore improper and should be withdrawn.

Finally, the office action rejects claim 19 under 35 U.S.C. § 103 as being unpatentable over Jain, Kenigsberg and further in view of Zarychta. However, claim 16 has been amended to make it clearly patentable over any hypothetical combination of Jain and Kenigsberg as set forth above. Zarychta is only cited for the proposition that it teaches the use of a radiopaque marker. Therefore, because not hypothetical combination of Jain and Kenigsberg establishes a *prima facie* case of obviousness for claim 16 and because Zarychta cannot supplement these two references in terms of their structural deficiencies regarding claim 16, no hypothetical combination of these three references can establish a *prima facie* case of obviousness with respect to dependent claim 19. Therefore, because of the standards of §§ 2142 and 2143 have not been satisfied, the rejection of claim 19 is improper and should be withdrawn.

An early indicating the allowability of this application and all pending claims is earnestly solicited.

The Commissioner is authorized to charge any fee deficiency required by this paper, or credit any overpayment, to Deposit Account No. 13-2855.

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